

**IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF ILLINOIS
EASTERN DIVISION**

IN RE: TEPEZZA MARKETING, SALES
PRACTICES, AND PRODUCTS LIABILITY
LITIGATION

No. 1:23-cv-03568
MDL No. 3079

This Document Relates to:

Judge Thomas M. Durkin

Egger, Case No. 1:23-cv-15306

Chief Magistrate Judge M. David Weisman

DEFENDANT HORIZON THERAPEUTICS USA, INC.’S
ANSWER AND JURY DEMAND

Pursuant to Rule 12 of the Federal Rules of Civil Procedure, Defendant Horizon Therapeutics USA, Inc. (“Horizon”), by and through its counsel, respectfully responds by generally denying all allegations in the First Amended Complaint with Jury Demand (“the Complaint”) of plaintiff Consuelo Egger, except as set forth below. Silence as to any allegations shall constitute a denial.

1. The allegations in Paragraph 1 of the Complaint constitute legal conclusions to which no response is required. To the extent that a response is required, Horizon denies each and every allegation contained in Paragraph 1 of the Complaint.

2. Horizon admits that it manufactures and sells Tepezza[®] according to its approved prescribing information and approved indications for use. Horizon is unclear as to the meaning of the term “promoted” and therefore denies the same. Horizon denies each and every remaining allegation in Paragraph 2.

3. Horizon denies each and every allegation in Paragraph 3 of the Complaint.

4. The allegations in Paragraph 4 constitute legal conclusions to which no response is required. To the extent that a response is required, Horizon denies each and every allegation in Paragraph 4 of the Complaint.

5. The allegations in Paragraph 5 constitute legal conclusions to which no response is required. To the extent that a response is required, Horizon denies each and every allegation in Paragraph 5 of the Complaint.

6. The allegations in Paragraph 6 constitute legal conclusions to which no response is required. To the extent a response is required, Horizon denies each and every allegation in Paragraph 6 of the Complaint. Horizon lacks sufficient knowledge or information to form a belief as to the truth of the allegation regarding plaintiff's first infusion of Tepezza[®] and therefore denies the same. Horizon denies the allegations in Paragraph 6 of the Complaint to the extent that they mischaracterize the FDA-approved prescribing information for Tepezza[®], which speaks for itself. Horizon denies that Tepezza[®]'s FDA-approved labeling is or was ever inadequate.

7. Horizon denies each and every allegation in Paragraph 7 of the Complaint. Horizon specifically denies that it proximately caused plaintiff any injuries or damages.

8. Paragraph 8 of the Complaint contains no allegations and thus no response is required.

9. Horizon lacks sufficient knowledge or information to form a belief as to the truth of the allegations in Paragraph 9 of the Complaint concerning plaintiff's residency and claimed use of Tepezza[®] and therefore denies the same. Horizon denies each and every remaining allegation in Paragraph 9, including that Tepezza[®] caused any injury to plaintiff.

10. Horizon lacks sufficient knowledge or information to form a belief as to the truth of the allegations in Paragraph 10 of the Complaint and therefore denies the same.

11. Horizon denies each and every allegation in Paragraph 11 of the Complaint. Horizon denies that Tepezza[®]'s FDA-approved labeling is or was ever inadequate.

12. Horizon lacks sufficient knowledge or information to form a belief as to the truth of the allegations, plaintiff's alleged diagnoses, in Paragraph 12 of the Complaint and therefore denies the same. Horizon denies that plaintiff's alleged diagnoses were the result of plaintiff's Tepezza infusions. Horizon denies each and every remaining allegation in Paragraph 12 of the Complaint.

13. The allegations in Paragraph 13 constitute legal conclusions to which no response is required. To the extent that a response is required, Horizon denies the same. Horizon specifically denies that Tepezza[®] proximately caused plaintiff any injuries or damages.

14. Horizon admits that it is a Delaware corporation with its principal place of business located in Deerfield, Illinois. Horizon denies each and every remaining allegation in Paragraph 14 of the Complaint.

15. Horizon admits that it was, at certain times, jointly owned by Horizon Therapeutics Capital, Ltd., established in Ireland, and Horizon Therapeutics Finance SARL, established in Luxembourg. Horizon further admits that at certain times, Horizon Therapeutics Capital, Ltd. Is wholly owned by Horizon Therapeutics Holdings, Ltd., establish in Ireland, and Horizon Therapeutics Holdings, Ltd., is wholly owned by Horizon Therapeutics PLC, established in Ireland. Horizon denies each and every remaining allegation in Paragraph 15 of the Complaint.

16. Horizon admits that it became a wholly owned subsidiary of Amgen, Inc., a Delaware corporation, on October 6, 2023. Horizon denies each and every remaining allegation in Paragraph 16 of the Complaint.

17. Horizon admits that at various times Horizon sold Tepezza[®] in the United States according to its approved prescribing information and approved indications for use. Horizon denies each and every remaining allegation in Paragraph 17 of the Complaint.

18. Horizon lacks sufficient knowledge or information to determine what time periods plaintiff asserts and therefore Horizon is unable to respond to the allegations in Paragraph 18 of the Complaint. Moreover, “substantial revenue” is a legal term of art, and the legal conclusions contained therein does not require an answer. Answering further, Horizon avers that it conducts business in the state of California and Florida and denies any remaining allegations in Paragraph 18 of the Complaint.

19. Horizon admits that it holds a Biologic License Application (“BLA”) for Tepezza[®]. Horizon denies each and every remaining allegation in Paragraph 19 of the Complaint.

20. Horizon lacks sufficient knowledge or information to determine what time periods plaintiff asserts are “[a]t all relevant times” and therefore Horizon is unable to respond to the allegations in Paragraph 20 of the Complaint. To the extent a response is required, Horizon admits that at times it distributed and sold Tepezza[®] in the United States. Horizon denies each and every remaining allegation in Paragraph 20 of the Complaint.

21. The allegations in Paragraph 21 constitute legal conclusions to which no response is required. To the extent that a response is required, Horizon denies the remaining allegations in Paragraph 21 of the Complaint.

22. The allegations in Paragraph 22 of the Complaint legal conclusions to which no response is required. To the extent that a response is required, Horizon denies the remaining allegations in Paragraph 22 of the Complaint.

23. The allegations in Paragraph 23 of the Complaint constitute legal conclusions to which no response is required. To the extent that a response is required, Horizon denies each and every allegation in Paragraph 23 of the Complaint.

24. The allegations in Paragraph 24 of the Complaint constitute legal conclusions to which no response is required. To the extent that a response is required, Horizon denies each and every allegation in Paragraph 24 of the Complaint.

25. Horizon admits that plaintiff has purported to file suit for damages but denies any liability to plaintiff. Horizon denies each and every remaining allegation in Paragraph 25 of the Complaint.

26. Horizon lacks sufficient knowledge or information to determine what time periods plaintiff asserts are “[a]t all relevant times” and therefore Horizon is unable to respond to the allegations in Paragraph 26 of the Complaint. Horizon admits that at various times it marketed, distributed, and sold Tepezza[®] according to its approved prescribing information and approved indications for use in the United States. Horizon denies each and every remaining allegation contained in Paragraph 26 of the Complaint.

27. Horizon denies each and every allegation in Paragraph 27 of the Complaint.

28. Horizon admits that thyroid eye disease (“TED”), at times, may involve progressive inflammation in the tissues around the eyes, may cause the eyelids to become red, swollen, and uncomfortable and the eyes can push forward or bulge (“proptosis”). Answering further, to the extent the allegations in Paragraph 28 refer to extrinsic documents not attached to or part of this Complaint, Horizon states that such documents speak for themselves. Horizon denies each and every remaining allegation in Paragraph 28 of the Complaint.

29. Horizon admits that TED is a serious, progressive and rare condition that can lead to permanent and vision-impairing consequences. Answering further, to the extent the allegations in Paragraph 29 of the Complaint refer to extrinsic documents not attached to or part of this

Complaint, Horizon states that such documents speak for themselves. Horizon denies each and every remaining allegation in Paragraph 29 of the Complaint.

30. The allegations in Paragraph 30 of the Complaint constitute attorney characterizations and are accordingly denied. Answering further, to the extent the allegations in Paragraph 30 of the Complaint refer to extrinsic documents not attached to or part of this Complaint, Horizon states that such documents speak for themselves.

31. Horizon admits that the signs and symptoms of TED may include redness, irritation, discomfort of the eyes or eyelids, dry eyes, and pain when moving the eyes, among other symptoms. Horizon further also admits that eyelid retraction, is common and that symptoms of TED can include exophthalmos or proptosis, loss of vision, blurred vision, diplopia, strabismus, chronic bloodshot, red, or conjunctival injection eyes, watery eyes due to excessive formation of tears, swelling near the upper and lower eyelids, an intolerance of bright lights, and difficulty moving the eyeballs. Horizon denies each and every allegation in Paragraph 31 of the Complaint inconsistent with its averments above.

32. Horizon admits that like most auto-immune disorders, TED may go through active phases where inflammatory symptoms are present, as well as inactive phases, where active inflammation reduces. Horizon further admits that disease activity occurring during active phases may lead to permanent damage to the tissues surrounding the eye, including fibrosis. Horizon denies each and every remaining allegation in Paragraph 32 of the Complaint.

33. Horizon admits that TED may occur in patients with Graves' disease, an autoimmune disease that affects the thyroid, skin, and tissues surrounding the eyes. Horizon further admits that TED, at times, can occur in people with an overactive or underactive thyroid

(hyperthyroidism and or hypothyroidism). Horizon denies each and every remaining allegation in Paragraph 33 of the Complaint.

34. Horizon admits that some individuals with TED have been treated with corticosteroids to reduce inflammation and swelling, radiation therapy, dark sunglasses to treat sensitivity to light, ointments, artificial tears, and/or prisms attached to glasses. Horizon denies each and every remaining allegation in Paragraph 34 of the Complaint.

35. Horizon admits that some individuals with TED may require surgical procedures which include orbital decompressions, strabismus, and lid procedures. Horizon denies each and every remaining allegation in Paragraph 35 of the Complaint.

36. The allegations in Paragraph 36 of the Complaint constitute attorney characterizations and are accordingly denied. Answering further, to the extent the allegations in Paragraph 36 of the Complaint refer to extrinsic documents not attached to or part of this Complaint, Horizon states that such documents speak for themselves. Horizon denies the allegations in Paragraph 36 of the Complaint to the extent they misstate or mischaracterize such documents.

37. Horizon admits the allegations in Paragraph 37 of the Complaint.

38. The allegations in Paragraph 38 of the Complaint constitute legal conclusions to which no response is required. To the extent a response is required, Horizon denies each and every allegation in Paragraph 38 of the Complaint.

39. Horizon admits the allegations in Paragraph 39 of the Complaint.

40. Horizon admits the allegations in Paragraph 40 of the Complaint.

41. Horizon admits that it submitted the Biologic License Application (BLA: 761143) for teprotumumab-trwb to FDA in 2019. Horizon denies each and every allegation in Paragraph 41 of the Complaint inconsistent with its specific averment above.

42. Horizon admits that the United States Food and Drug Administration (“FDA”) approved Tepezza[®] in January 2020 as safe and effective for treatment of thyroid eye disease. Horizon admits that Tepezza[®] was the first approved drug to treat TED. Horizon further admits that Tepezza[®] is an insulin-like growth factor-1 receptor inhibitor (IGF-1R). Horizon denies the allegations in Paragraph 42 of the Complaint to the extent that they mischaracterize the FDA-approved prescribing information for Tepezza[®], which speaks for itself. Horizon denies each and every allegation in Paragraph 42 inconsistent with its specific averment above.

43. The allegations in Paragraph 43 of the Complaint constitute attorney characterizations and are accordingly denied. To the extent that Paragraph 43 refers to documents not attached to or part of this Complaint, Horizon states that such documents speak for themselves. Horizon denies the allegations in Paragraph 43 of the Complaint to the extent they misstate or mischaracterize such documents.

44. The allegations in Paragraph 44 of the Complaint constitute attorney characterizations and are accordingly denied. To the extent that the allegations in Paragraph 44 refer to documents not attached to or part of this Complaint, Horizon states that such documents speak for themselves. Horizon denies the allegations in Paragraph 44 of the Complaint to the extent they misstate or mischaracterize such documents.

45. The allegations in Paragraph 45 of the Complaint constitute attorney characterizations and are accordingly denied. Answering further, to the extent that the allegations

in Paragraph 45 refer to documents not attached to or part of this Complaint, Horizon states that such documents speak for themselves.

46. Horizon denies that it “failed to conduct tests to determine the mechanism of action of the drug” as required by the U.S. Food and Drug Administration (“FDA”) and in accordance with the Federal Food, Drug, and Cosmetic Act (FDCA), 21 U.S.C. §§ 301-392. Answering further, to the extent that the allegations in Paragraph 46 refer to documents not attached to or part of this Complaint, Horizon states that such documents speak for themselves. Horizon denies the allegations in Paragraph 46 of the Complaint to the extent they misstate or mischaracterize such documents.

47. To the extent that the allegations in Paragraph 47 refer to documents not attached to or part of this Complaint, Horizon states that such documents speak for themselves. Horizon denies the allegations in Paragraph 47 of the Complaint to the extent they misstate or mischaracterize such documents. Horizon denies each and every remaining allegation in Paragraph 47 of the Complaint.

48. To the extent that the allegations in Paragraph 48 refer to documents not attached to or part of this Complaint, Horizon states that such documents speak for themselves. Horizon denies the allegations in Paragraph 48 of the Complaint to the extent they misstate or mischaracterize such documents. Horizon denies each and every remaining allegation in Paragraph 48 of the Complaint.

49. To the extent that the allegations in Paragraph 49 refer to documents not attached to or part of this Complaint, Horizon states that such documents speak for themselves. Horizon denies the allegations in Paragraph 49 of the Complaint to the extent they misstate or

mischaracterize such documents. Horizon denies each and every remaining allegation in Paragraph 49 of the Complaint.

50. The allegations in Paragraph 50 of the Complaint constitute attorney characterizations and are accordingly denied.

51. Horizon denies each and every allegation contained in Paragraph 51 of the Complaint. Answering further, to the extent that the allegations in Paragraph 51 refer to documents not attached to or part of this Complaint, Horizon states that such documents speak for themselves. Horizon denies the allegations in Paragraph 51 of the Complaint to the extent they misstate or mischaracterize such documents.

52. Horizon admits that the Tepezza[®] label in January 2020 listed hearing loss in Section 6.1 Clinical Trials Experience. Horizon further admits that the January 2020 Tepezza[®] label listed hearing impairment in Table 1 “Adverse Reactions Occurring in 5% or More of Patients Treated with TEPEZZA and Greater Incidence than Placebo” in Section 6.1. Horizon also admits that the Tepezza[®] January 2020 label lists hearing impairment to have occurred in 8 patients treated with Tepezza[®] and 0 in the placebo group. Horizon further admits that hearing impairment in the January 2020 label was defined to include deafness, eustachian tube dysfunction, hyperacusis, hypoacusis, and autophony. Horizon denies each and every remaining allegation contained in Paragraph 52 of the Complaint. Answering further, to the extent that the allegations in Paragraph 52 refer to documents not attached to or part of this Complaint, Horizon states that such documents speak for themselves. Horizon denies the allegations in Paragraph 52 of the Complaint to the extent they misstate or mischaracterize such documents.

53. Horizon denies each and every allegation contained in Paragraph 53 of the Complaint.

54. Horizon denies each and every allegation contained in Paragraph 54 of the Complaint. Answering further, to the extent that the allegations in Paragraph 54 refer to documents not attached to or part of this Complaint, Horizon states that such documents speak for themselves. Horizon denies the allegations in Paragraph 54 of the Complaint to the extent they misstate or mischaracterize such documents.

55. Horizon denies each and every allegation contained in Paragraph 55 of the Complaint. Answering further, to the extent that the allegations in Paragraph 55 refer to documents not attached to or part of this Complaint, Horizon states that such documents speak for themselves. Horizon denies the allegations in Paragraph 55 of the Complaint to the extent they misstate or mischaracterize such documents.

56. Horizon denies each and every allegation contained in Paragraph 56 of the Complaint.

57. Horizon denies each and every allegation contained in Paragraph 57 of the Complaint.

58. Horizon denies each and every allegation contained in Paragraph 58 of the Complaint.

59. Horizon denies each and every allegation contained in Paragraph 59 of the Complaint. Answering further, to the extent that the allegations in Paragraph 59 refer to documents not attached to or part of this Complaint, Horizon states that such documents speak for themselves. Horizon denies the allegations in Paragraph 59 of the Complaint to the extent they misstate or mischaracterize such documents.

60. Horizon denies each and every allegation contained in Paragraph 60 of the Complaint.

61. Horizon admits that Dr. Wenzhong “Jerry” Liu served as Executive Medical Director, Clinical Development, at Horizon. Horizon denies each and every remaining allegation contained in Paragraph 61 of the Complaint.

62. Horizon lacks sufficient knowledge or information to form a belief as to the truth of the allegations in Paragraph 62 of the Complaint and therefore denies the same.

63. Horizon lacks sufficient knowledge or information to form a belief as to the truth of the allegations in Paragraph 63 of the Complaint and therefore denies the same.

64. Horizon denies each and every allegation in Paragraph 64 of the Complaint.

65. Horizon denies each and every allegation contained in Paragraph 65 of the Complaint.

66. Horizon admits that in 2023, the studies of Tepezza[®] listed in Paragraph 66 of the Complaint were underway, planned, or completed for review. Horizon denies each and every remaining allegation contained in Paragraph 66 of the Complaint.

67. Horizon admits that the Phase 2 and 3 TED studies were provided to FDA to seek initial approval. To the extent that the allegations in Paragraph 67 refer to documents not attached to or part of this Complaint, Horizon states that such documents speak for themselves. Horizon denies the allegations in Paragraph 67 of the Complaint to the extent they misstate or mischaracterize such documents. Horizon denies each and every remaining allegation in Paragraph 67 of the Complaint

68. Horizon denies each and every allegation contained in Paragraph 68 of the Complaint.

69. Horizon denies each and every allegation contained in Paragraph 69 of the Complaint.

70. Horizon denies each and every allegation contained in Paragraph 70 of the Complaint.

71. Horizon denies each and every allegation contained in Paragraph 71 of the Complaint.

72. Horizon admits Dr. Liu's employment at Horizon ended in June 2023. Horizon denies each and every remaining allegation contained in Paragraph 72 of the Complaint.

73. Horizon admits that Dr. Liu purported to bring a wrongful-termination lawsuit against Horizon in California Superior Court in San Diego. Horizon denies each and every remaining allegation contained in Paragraph 73 of the Complaint.

74. Horizon admits that in July 2023, the Tepezza[®] label was updated to include a Warning and Precaution relating to hearing impairment. Horizon denies each and every remaining allegation in Paragraph 74 of the Complaint.

75. Horizon denies each and every allegation in Paragraph 75 of the Complaint.

76. The allegations in Paragraph 76 constitute attorney characterizations and are accordingly denied.

77. Horizon denies each and every allegation contained in Paragraph 77 of the Complaint, including each of its subparts. Answering further, to the extent that the allegations in Paragraph 77 refer to documents not attached to or part of this Complaint, Horizon states that such documents speak for themselves. Horizon denies the allegations in Paragraph 77 of the Complaint to the extent they misstate or mischaracterize such documents.

78. Horizon lacks sufficient information to form a belief as to the truth of the allegations in Paragraph 78 of the Complaint and therefore denies the same.

79. Horizon denies each and every allegation contained in Paragraph 79 of the Complaint, including each of its subparts. Answering further, to the extent that the allegations in Paragraph 79 refer to documents not attached to or part of this Complaint, Horizon states that such documents speak for themselves. Horizon denies the allegations in Paragraph 79 of the Complaint to the extent they misstate or mischaracterize such documents.

80. Horizon lacks sufficient information to form a belief as to the truth of the allegations in Paragraph 80 of the Complaint and therefore denies the same.

81. Horizon denies each and every allegation contained in Paragraph 81 of the Complaint, including each of its subparts. Answering further, to the extent that the allegations in Paragraph 81 refer to documents not attached to or part of this Complaint, Horizon states that such documents speak for themselves. Horizon denies the allegations in Paragraph 81 of the Complaint to the extent they misstate or mischaracterize such documents.

82. Horizon lacks sufficient information to form as belief as to the truth of the allegations in Paragraph 82 of the Complaint and therefore denies the same.

83. Horizon denies each and every allegation contained in Paragraph 83 of the Complaint. Answering further, to the extent that the allegations in Paragraph 83 refer to documents not attached to or part of this Complaint, Horizon states that such documents speak for themselves. Horizon denies the allegations in Paragraph 83 of the Complaint to the extent they misstate or mischaracterize such documents.

84. Horizon denies each and every allegation contained in Paragraph 84 of the Complaint, including each of its subparts. Answering further, to the extent that the allegations in Paragraph 84 refer to documents not attached to or part of this Complaint, Horizon states that such

documents speak for themselves. Horizon denies the allegations in Paragraph 84 of the Complaint to the extent they misstate or mischaracterize such documents.

85. Horizon denies each and every allegation contained in Paragraph 85 of the Complaint, including each of its subparts. Answering further, to the extent that the allegations in Paragraph 85 refer to documents not attached to or part of this Complaint, Horizon states that such documents speak for themselves. Horizon denies the allegations in Paragraph 85 of the Complaint to the extent they misstate or mischaracterize such documents.

86. Horizon lacks sufficient information as to form a belief as to the truth of the allegations in Paragraph 86 and therefore denies the same.

87. Horizon denies each and every allegation contained in Paragraph 87 of the Complaint. Answering further, to the extent the allegations in Paragraph 87 refer to documents not attached to or part of this Complaint, Horizon states that such documents speak for themselves.

88. Horizon denies each and every allegation in Paragraph 88 of the Complaint.

89. The allegations in Paragraph 89 of the Complaint constitute legal conclusions to which no response is required. To the extent a response is deemed required, Horizon denies each and every allegation in Paragraph 89 of the Complaint.

90. The allegations in Paragraph 90 of the Complaint constitute legal conclusions to which no response is required. To the extent that a response is required Horizon denies each and every allegation contained in Paragraph 90 of the Complaint.

91. The allegations in Paragraph 91 of the Complaint constitute legal conclusions to which no response is required. To the extent that a response is required, Horizon denies each and every allegation contained in Paragraph 91 of the Complaint.

92. The allegations in Paragraph 92 of the Complaint constitute legal conclusions to which no response is required. To the extent that a response is required, Horizon denies each and every allegation contained in Paragraph 92 of the Complaint. Answering further, to the extent that Paragraph 92 refers to extrinsic documents not attached to or part of this Complaint, Horizon states that such documents speak for themselves. Horizon denies Paragraph 92 of the Complaint to the extent it misstates or mischaracterizes such documents.

93. Horizon denies each and every allegation contained in Paragraph 93 of the Complaint. Answering further, to the extent Paragraph 93 refers to extrinsic documents not attached to or part of this Complaint, Horizon states that such documents speak for themselves. Horizon denies Paragraph 93 of the Complaint to the extent it misstates or mischaracterizes such documents.

94. Horizon denies each and every allegation in in Paragraph 94 of the Complaint.

95. Horizon admits that it conducted an expanded access protocol, Phase 3b, Multicenter, Open-label, Single-Arm, Expanded Access Protocol of TEPROTUMUMAB (HZN-001) (NCT04040894). Horizon denies each and every remaining allegation in Paragraph 95 of the Complaint.

96. Horizon admits that it conducted a Phase 1 clinical study, A Randomized, Double-Blind, Placebo-Controlled, Repeat-Dose, Multicenter Study to Evaluate the Safety, Tolerability, Pharmacokinetics and Pharmacodynamics, and Explore Efficacy of TEPEZZA in Patients with Diffuse Cutaneous Systemic Sclerosis (HZNP-TEP-001) and terminated the study in 2018. Horizon denies each and every remaining allegation in Paragraph 96 of the Complaint.

97. Horizon admits that it conducted a Phase 4 study, A Study Evaluating TEPEZZA Treatment in Patients with Chronic (Inactive) Thyroid Eye Disease (NCT04583735). Answering

further, to the extent Paragraph 97 refers to extrinsic documents not attached to or part of this Complaint, Horizon states that such documents speak for themselves. Horizon denies Paragraph 97 of the Complaint to the extent it misstates or mischaracterizes such documents.

98. Horizon denies each and every allegation in Paragraph 98 of the Complaint.

99. Horizon denies each and every allegation in Paragraph 99 of the Complaint, including each of its subparts. Answering further, to the extent Paragraph 99 refers to extrinsic documents not attached to or part of this Complaint, Horizon states that such documents speak for themselves. Horizon denies Paragraph 99 of the Complaint to the extent it misstates or mischaracterizes such documents.

100. Horizon denies each and every allegation in Paragraph 100 of the Complaint. Answering further, to the extent that Paragraph 100 refers to extrinsic documents not attached to or part of this Complaint, Horizon states that such documents speak for themselves. Horizon denies Paragraph 100 of the Complaint to the extent it misstates or mischaracterizes such documents.

101. Horizon admits in October 2021, an Open-Label Clinical Extension Study (OPTIC-X) was published online authored by Douglas RS, et. al., titled *Teprotumumab Efficacy, Safety, Durability in Longer-Duration Thyroid Eye Disease and Re-treatment: OPTIC-X*, Ophthalmology 2022;129-438-449 (e-pub Oct. 2021). Horizon denies each and every remaining allegation in Paragraph 101 of the Complaint.

102. Horizon denies each and every allegation in Paragraph 102 of the Complaint.

103. Horizon admits teprotumumab-trbw (Tepezza[®]) is an insulin-like growth factor I receptor. The remaining allegations in Paragraph 103 of the Complaint constitute legal conclusions to which no response is required. To the extent that a response is required, Horizon denies each and every allegation in Paragraph 103 of the Complaint.

104. Horizon denies each and every allegation in Paragraph 104 of the Complaint. Answering further, to the extent Paragraph 104 refers to extrinsic documents not attached to or part of this Complaint, Horizon states that such documents speak for themselves. Horizon denies Paragraph 104 of the Complaint to the extent it misstates or mischaracterizes such documents.

105. The allegations in Paragraph 105 constitute attorney characterizations, and are accordingly denied. Answering further, to the extent Paragraph 105 refers to extrinsic documents not attached to or part of this Complaint, Horizon states that such documents speak for themselves. Horizon denies Paragraph 105 of the Complaint to the extent it misstates or mischaracterizes such documents.

106. The allegations in Paragraph 106 of the Complaint constitute legal conclusions to which no response is required. To the extent that a response is required, Horizon denies each and every allegation in Paragraph 106 of the Complaint.

107. Horizon denies each and every allegation in Paragraph 107 of the Complaint. Answering further, to the extent Paragraph 107 refers to extrinsic documents not attached to or part of this Complaint, Horizon states that such documents speak for themselves. Horizon denies Paragraph 107 of the Complaint to the extent it misstates or mischaracterizes such documents.

108. The allegations in Paragraph 108 of the Complaint constitute attorney characterizations and are accordingly denied. Answering further, to the extent Paragraph 108 refers to extrinsic documents not attached to or part of this Complaint, thus Horizon states that such documents speak for themselves. Horizon denies Paragraph 108 of the Complaint to the extent it misstates or mischaracterizes such documents.

109. The allegations in Paragraph 109 of the Complaint constitute attorney characterizations and are accordingly denied. Answering further, to the extent Paragraph 109 refers

to extrinsic documents not attached to or part of this Complaint, thus Horizon states that such documents speak for themselves. Horizon denies Paragraph 109 of the Complaint to the extent it misstates or mischaracterizes such documents.

110. The allegations in Paragraph 110 of the Complaint constitute attorney characterizations and are accordingly denied. Answering further, to the extent Paragraph 110 refers to extrinsic documents not attached to or part of this Complaint, Horizon states that such documents speak for themselves. Horizon denies Paragraph 110 of the Complaint to the extent it misstates or mischaracterizes such documents.

111. The allegations in Paragraph 111 of the Complaint constitute attorney characterizations and are accordingly denied. Answering further, to the extent Paragraph 111 refers to extrinsic documents not attached to or part of this Complaint, thus Horizon states that such documents speak for themselves. Horizon denies Paragraph 111 of the Complaint to the extent it misstates or mischaracterizes such documents.

112. The allegations in Paragraph 112 of the Complaint constitute attorney characterizations and are accordingly denied. Answering further, to the extent Paragraph 112 refers to extrinsic documents not attached to or part of this Complaint, Horizon states that such documents speak for themselves. Horizon denies Paragraph 112 of the Complaint to the extent it misstates or mischaracterizes such documents.

113. The allegations in Paragraph 113 of the Complaint constitute attorney characterizations and are accordingly denied. Answering further, to the extent that Paragraph 113 refers to extrinsic documents not attached to or part of this Complaint, Horizon states that such documents speak for themselves. Horizon denies Paragraph 113 of the Complaint to the extent it misstates or mischaracterizes such documents.

114. The allegations in Paragraph 114 of the Complaint constitute attorney characterizations and are accordingly denied. Answering further, to the extent Paragraph 114 refers to extrinsic documents not attached to or part of this Complaint, Horizon states that such documents speak for themselves. Horizon denies Paragraph 114 of the Complaint to the extent it misstates or mischaracterizes such documents.

115. The allegations in Paragraph 115 of the Complaint constitute attorney characterizations and are accordingly denied. Answering further, to the extent Paragraph 115 refers to extrinsic documents not attached to or part of this Complaint, Horizon states that such documents speak for themselves. Horizon denies Paragraph 115 of the Complaint to the extent it misstates or mischaracterizes such documents.

116. The allegations in Paragraph 116 of the Complaint constitute attorney characterizations and are accordingly denied. Answering further, to the extent Paragraph 116 refers to extrinsic documents not attached to or part of this Complaint, Horizon states that such documents speak for themselves. Horizon denies Paragraph 116 of the Complaint to the extent it misstates or mischaracterizes such documents.

117. The allegations in Paragraph 117 of the Complaint constitute attorney characterizations and are accordingly denied. Answering further, to the extent that Paragraph 117 refers to extrinsic documents not attached to or part of this Complaint, Horizon states that such documents speak for themselves. Horizon denies Paragraph 117 of the Complaint to the extent it misstates or mischaracterizes such documents.

118. Horizon admits that it in January 2023, it submitted supplement 023 to BLA 761143 in January 2023 for Tepezza[®]. Answering further, to the extent Paragraph 118 refers to extrinsic documents not attached to or part of this Complaint, Horizon states that such documents speak for

themselves. Horizon denies Paragraph 118 of the Complaint to the extent it misstates or mischaracterizes such documents. Horizon denies each and every remaining allegation in Paragraph 118 of the Complaint.

119. The allegations in Paragraph 119 constitute attorney characterizations and are accordingly denied. Answering further, to the extent Paragraph 119 refers to extrinsic documents not attached to or part of this Complaint, Horizon states that such documents speak for themselves. Horizon denies Paragraph 119 of the Complaint to the extent it misstates or mischaracterizes such documents.

120. Horizon denies each and every allegation contained in Paragraph 120 of the Complaint.

121. The allegations in Paragraph 121 of the Complaint constitute legal conclusions to which no response is required. To the extent that a response is required, Horizon denies each and every allegation in Paragraph 121 of the Complaint.

122. The allegations in Paragraph 122 of the Complaint constitute attorney characterizations and are accordingly denied. Answering further, to the extent Paragraph 122 refers to extrinsic documents not attached to or part of this Complaint, Horizon states that such documents speak for themselves. Horizon denies Paragraph 122 of the Complaint to the extent it misstates or mischaracterizes such documents.

123. The allegations in Paragraph 123 of the Complaint constitute attorney characterizations and are accordingly denied. Answering further, to the extent Paragraph 123 refers to extrinsic documents not attached to or part of this Complaint, Horizon states that such documents speak for themselves. Horizon denies Paragraph 123 of the Complaint to the extent it misstates or mischaracterizes such documents.

124. The allegations in Paragraph 124 of the Complaint constitute attorney characterizations and are accordingly denied. Answering further, to the extent Paragraph 124 refers to extrinsic documents not attached to or part of this Complaint, Horizon states that such documents speak for themselves. Horizon denies Paragraph 124 of the Complaint to the extent it misstates or mischaracterizes such documents.

125. Horizon denies each and every allegation contained in Paragraph 125 of the Complaint.

126. Horizon denies each and every allegation contained in Paragraph 126 of the Complaint.

127. Horizon denies each and every allegation in Paragraph 127 of the Complaint. Answering further, to the extent that Paragraph 127 refers to extrinsic documents not attached to or part of this Complaint, Horizon states that such documents speak for themselves. Horizon denies Paragraph 127 of the Complaint to the extent it misstates or mischaracterizes such documents.

128. The allegations in Paragraph 128 of the Complaint constitute attorney characterizations and are accordingly denied. Answering further, to the extent Paragraph 128 refers to extrinsic documents not attached to or part of this Complaint, Horizon states that such documents speak for themselves. Horizon denies Paragraph 128 of the Complaint to the extent it misstates or mischaracterizes such documents.

129. The allegations in Paragraph 129 of the Complaint constitute attorney characterizations and are accordingly denied. Answering further, to the extent Paragraph 129 refers to extrinsic documents not attached to or part of this Complaint, Horizon states that such documents speak for themselves. Horizon denies Paragraph 129 of the Complaint to the extent it misstates or mischaracterizes such documents.

130. Horizon denies each and every allegation contained in Paragraph 130 of the Complaint.

131. Horizon denies each and every allegation contained in Paragraph 131 of the Complaint.

132. Horizon denies each and every allegation contained in Paragraph 132 of the Complaint.

133. Horizon denies each and every allegation contained in Paragraph 133 of the Complaint.

134. The allegations in Paragraph 134 of the Complaint constitute attorney characterizations and are accordingly denied. Answering further, to the extent Paragraph 134 refers to extrinsic documents not attached to or part of this Complaint, Horizon states that such documents speak for themselves. Horizon denies Paragraph 134 of the Complaint to the extent it misstates or mischaracterizes such documents.

135. The allegations in Paragraph 135 of the Complaint constitute attorney characterizations and are accordingly denied. Answering further, to the extent Paragraph 135 refers to extrinsic documents not attached to or part of this Complaint, Horizon states that such documents speak for themselves. Horizon denies Paragraph 135 of the Complaint to the extent it misstates or mischaracterizes such documents.

136. The allegations in Paragraph 136 of the Complaint constitute legal conclusions for which no response is required. To the extent that a response is required, Horizon denies each and every allegation in Paragraph 136 of the Complaint.

137. The allegations in Paragraph 137 of the Complaint constitute legal conclusions for which no response is required. To the extent that a response is required, Horizon denies each and every allegation in Paragraph 137 of the Complaint.

138. Horizon denies each and every allegation contained in Paragraph 138 of the Complaint.

139. Horizon denies each and every allegation contained in Paragraph 139 of the Complaint.

140. Horizon admits that the Tepezza[®] label was updated on July 17, 2023, to add Section 5.4 Hearing Impairment Including Hearing Loss. Horizon denies each and every remaining allegation in Paragraph 140 of the Complaint.

141. Horizon denies each and every allegation contained in Paragraph 141 of the Complaint.

142. Horizon denies each and every allegation contained in Paragraph 142 of the Complaint.

143. Horizon denies each and every allegation contained in Paragraph 143 of the Complaint.

144. Horizon denies each and every allegation contained in Paragraph 144 of the Complaint.

145. Horizon denies each and every allegation contained in Paragraph 145 of the Complaint. Answering further, to the extent Paragraph 145 refers to extrinsic documents not attached to or part of this Complaint, Horizon states that such documents speak for themselves. Horizon denies Paragraph 145 of the Complaint to the extent it misstates or mischaracterizes such documents.

146. The allegations in Paragraph 146 of the Complaint constitute attorney characterizations and are accordingly denied. Answering further, to the extent that Paragraph 146 refers to extrinsic documents not attached to or part of this Complaint, Horizon states that such documents speak for themselves. Horizon denies Paragraph 146 of the Complaint to the extent it misstates or mischaracterizes such documents.

147. Horizon denies each and every allegation contained in Paragraph 147 of the Complaint. Answering further, to the extent that Paragraph 147 refers to extrinsic documents not attached to or part of this Complaint, Horizon states that such documents speak for themselves. Horizon denies Paragraph 147 of the Complaint to the extent it misstates or mischaracterizes such documents.

148. Horizon denies each and every allegation contained in Paragraph 148 of the Complaint. Answering further, to the extent Paragraph 148 refers to extrinsic documents not attached to or part of this Complaint, Horizon states that such documents speak for themselves. Horizon denies Paragraph 148 of the Complaint to the extent it misstates or mischaracterizes such documents.

149. Horizon denies each and every allegation contained in Paragraph 149 of the Complaint.

150. The allegations in Paragraph 150 of the Complaint constitute attorney characterizations and are accordingly denied. Answering further, to the extent that Paragraph 150 refers to extrinsic documents not attached to or part of this Complaint, Horizon states that such documents speak for themselves. Horizon denies Paragraph 150 of the Complaint to the extent it misstates or mischaracterizes such documents.

151. Horizon denies each and every allegation contained in Paragraph 151 of the Complaint. Answering further, to the extent that Paragraph 151 refers to extrinsic documents not attached to or part of this Complaint, Horizon states that such documents speak for themselves. Horizon denies Paragraph 151 of the Complaint to the extent it misstates or mischaracterizes such documents.

152. Horizon denies each and every allegation contained in Paragraph 152 of the Complaint. Answering further, to the extent that Paragraph 152 refers to extrinsic documents not attached to or part of this Complaint, Horizon states that such documents speak for themselves. Horizon denies Paragraph 152 of the Complaint to the extent it misstates or mischaracterizes such documents.

153. Horizon denies each and every allegation contained in Paragraph 153 of the Complaint. Answering further, to the extent that Paragraph 153 refers to extrinsic documents not attached to or part of this Complaint, Horizon states that such documents speak for themselves. Horizon denies Paragraph 153 of the Complaint to the extent it misstates or mischaracterizes such documents.

154. Horizon denies each and every allegation contained in Paragraph 154 of the Complaint. Answering further, to the extent that Paragraph 154 refers to extrinsic documents not attached to or part of this Complaint, Horizon states that such documents speak for themselves. Horizon denies Paragraph 154 of the Complaint to the extent it misstates or mischaracterizes such documents.

155. Horizon denies each and every allegation contained in Paragraph 155 of the Complaint.

156. Horizon denies each and every allegation contained in Paragraph 156 of the Complaint.

157. Horizon denies each and every allegation contained in Paragraph 157 of the Complaint.

158. Horizon denies each and every allegation contained in Paragraph 158 of the Complaint.

159. Horizon denies each and every allegation contained in Paragraph 159 of the Complaint.

160. Horizon denies each and every allegation contained in Paragraph 160 of the Complaint.

161. Horizon denies each and every allegation contained in Paragraph 161 of the Complaint. Answering further, to the extent that Paragraph 161 refers to extrinsic documents not attached to or part of this Complaint, Horizon states that such documents speak for themselves. Horizon denies Paragraph 161 of the Complaint to the extent it misstates or mischaracterizes such documents.

162. Horizon denies each and every allegation contained in Paragraph 162 of the Complaint.

163. Horizon denies each and every allegation contained in Paragraph 163 of the Complaint.

164. Horizon denies each and every allegation contained in Paragraph 164 of the Complaint.

165. Horizon denies each and every allegation contained in Paragraph 165 of the Complaint.

166. Horizon denies each and every allegation contained in Paragraph 166 of the Complaint.

167. Horizon denies each and every allegation contained in Paragraph 167 of the Complaint.

168. Horizon denies each and every allegation contained in Paragraph 168 of the Complaint.

169. Horizon denies each and every allegation contained in Paragraph 169 of the Complaint.

170. Horizon denies each and every allegation contained in Paragraph 170 of the Complaint.

171. Horizon denies each and every allegation contained in Paragraph 171 of the Complaint.

172. Horizon denies each and every allegation contained in Paragraph 172 of the Complaint.

173. Horizon denies each and every allegation contained in Paragraph 173 of the Complaint.

174. Horizon denies each and every allegation contained in Paragraph 174 of the Complaint.

175. Horizon denies each and every allegation contained in Paragraph 175 of the Complaint.

176. Horizon denies each and every allegation contained in Paragraph 176 of the Complaint.

177. Horizon denies each and every allegation contained in Paragraph 177 of the Complaint.

178. Horizon denies each and every allegation contained in Paragraph 178 of the Complaint.

179. Horizon denies each and every allegation contained in Paragraph 179 of the Complaint.

180. Horizon denies each and every allegation contained in Paragraph 180 of the Complaint.

181. Horizon denies each and every allegation contained in Paragraph 181 of the Complaint.

182. Horizon denies each and every allegation contained in Paragraph 182 of the Complaint.

183. Horizon denies each and every allegation contained in Paragraph 183 of the Complaint.

184. In response to Paragraph 184 of the Complaint, Horizon incorporates by references its responses to Paragraphs 1-183 of the Complaint as if set forth at length.

185. Horizon denies each and every allegation contained in Paragraph 185 of the Complaint.

186. Horizon denies each and every allegation contained in Paragraph 186 of the Complaint.

187. Horizon denies each and every allegation contained in Paragraph 187 of the Complaint.

188. Horizon denies each and every allegation contained in Paragraph 188 of the Complaint.

189. Horizon denies each and every allegation contained in Paragraph 189 of the Complaint.

190. Horizon denies each and every allegation contained in Paragraph 190 of the Complaint.

191. Horizon denies each and every allegation contained in Paragraph 191 of the Complaint.

192. Horizon denies each and every allegation contained in Paragraph 192 of the Complaint.

193. Horizon denies each and every allegation contained in Paragraph 193 of the Complaint.

194. Horizon denies each and every allegation contained in Paragraph 194 of the Complaint.

195. Horizon denies each and every allegation contained in Paragraph 195 of the Complaint.

196. Horizon denies each and every allegation contained in Paragraph 196 of the Complaint.

197. Horizon denies each and every allegation contained in Paragraph 197 of the Complaint, including each of its subparts.

198. Horizon denies each and every allegation contained in Paragraph 198 of the Complaint.

199. Horizon denies each and every allegation contained in Paragraph 199 of the Complaint.

200. Horizon denies each and every allegation contained in Paragraph 200 of the Complaint.

201. Horizon denies each and every allegation contained in Paragraph 201 of the Complaint.

202. Horizon denies each and every allegation contained in Paragraph 202 of the Complaint.

203. Horizon denies each and every allegation contained in Paragraph 203 of the Complaint.

204. Horizon denies each and every allegation contained in Paragraph 204 of the Complaint.

205. Horizon denies each and every allegation contained in Paragraph 205 of the Complaint.

206. In response to Paragraph 206 of the Complaint, Horizon incorporates by references its responses to the allegations contained to Paragraphs 1-205 of the Complaint as if set forth at length.

207. Horizon denies each and every allegation contained in Paragraph 207 of the Complaint.

208. Horizon denies each and every allegation contained in Paragraph 208 of the Complaint.

209. Horizon denies each and every allegation contained in Paragraph 209 of the Complaint.

210. Horizon denies each and every allegation contained in Paragraph 210 of the Complaint.

211. Horizon denies each and every allegation contained in Paragraph 211 of the Complaint, including each of its subparts.

212. Horizon denies each and every allegation contained in Paragraph 212 of the Complaint.

213. Horizon denies each and every allegation contained in Paragraph 213 of the Complaint.

214. Horizon lacks sufficient knowledge or information to form a belief as to the truth of the allegations in Paragraph 214 of the Complaint and therefore denies the same.

215. Horizon denies each and every allegation contained in Paragraph 215 of the Complaint.

216. Horizon denies each and every allegation contained in Paragraph 216 of the Complaint.

217. Horizon denies each and every allegation contained in Paragraph 217 of the Complaint.

218. Horizon denies each and every allegation contained in Paragraph 218 of the Complaint.

219. Horizon denies each and every allegation contained in Paragraph 219 of the Complaint.

220. Horizon denies each and every allegation contained in Paragraph 220 of the Complaint.

221. Horizon denies each and every allegation contained in Paragraph 221 of the Complaint.

222. Horizon denies each and every allegation contained in Paragraph 222 of the Complaint.

223. Horizon denies each and every allegation contained in Paragraph 223 of the Complaint.

224. In response to Paragraph 224 of the Complaint, Horizon incorporates by references its responses to the allegations contained in Paragraphs 1-223 of the Complaint as if set forth at length.

225. Per the Court's January 10, 2025 Memorandum Opinion and Order (ECF No. 25), the Court dismissed Claim 3 of plaintiff's Complaint (ECF No. 3). Accordingly, no response is required to Paragraph 225 of the Complaint. To the extent that a response is required, Horizon denies each and every allegation in Paragraph 225 of the Complaint.

226. Per the Court's January 10, 2025 Memorandum Opinion and Order (ECF No. 25), the Court dismissed Claim 3 of the Complaint (ECF No. 3). Accordingly, no response is required to Paragraph 226 of the Complaint. To the extent that a response is required, Horizon denies each and every allegation in Paragraph 226 of the Complaint.

227. Per the Court's January 10, 2025 Memorandum Opinion and Order (ECF No. 25), the Court dismissed Claim 3 of the Complaint (ECF No. 3). Accordingly, no response is required to Paragraph 227 of the Complaint. To the extent that a response is required, Horizon denies each and every allegation in Paragraph 227 of the Complaint.

228. Per the Court's January 10, 2025 Memorandum Opinion and Order (ECF No. 25), the Court dismissed Claim 3 of the Complaint (ECF No. 3). Accordingly, no response is required

to Paragraph 228 of the Complaints. To the extent that a response is required, Horizon denies each and every allegation in Paragraph 228 of the Complaint.

229. Per the Court's January 10, 2025 Memorandum Opinion and Order (ECF No. 25), the Court dismissed Claim 3 of the Complaint (ECF No. 3). Accordingly, no response is required to Paragraph 229 of the Complaint. To the extent that a response is required, Horizon denies each and every allegation in Paragraph 229 of the Complaint.

230. Per the Court's January 10, 2025 Memorandum Opinion and Order (ECF No. 25), the Court dismissed Claim 3 of the Complaint (ECF No. 3). Accordingly, no response is required to Paragraph 230 of the Complaint. To the extent that a response is required, Horizon denies each and every allegation in Paragraph 230 of the Complaint.

231. Per the Court's January 10, 2025 Memorandum Opinion and Order (ECF No. 25), the Court dismissed Claim 3 of the Complaint (ECF No. 3). Accordingly, no response is required to Paragraph 231 of the Complaint. To the extent that a response is required, Horizon denies each and every allegation in Paragraph 231 of the Complaint.

232. Per the Court's January 10, 2025 Memorandum Opinion and Order (ECF No. 25), the Court dismissed Claim 3 of the Complaint (ECF No. 3). Accordingly, no response is required to Paragraph 232 of the Complaint. To the extent that a response is required, Horizon denies each and every allegation in Paragraph 232 of the Complaint.

233. Per the Court's January 10, 2025 Memorandum Opinion and Order (ECF No. 25), the Court dismissed Claim 3 of the Complaint (ECF No. 3). Accordingly, no response is required to Paragraph 233 of the Complaint. To the extent that a response is required, Horizon denies each and every allegation in Paragraph 233 of the Complaint.

234. Per the Court's January 10, 2025 Memorandum Opinion and Order (ECF No. 25), the Court dismissed Claim 3 of the Complaint (ECF No. 3). Accordingly, no response is required to Paragraph 234 of the Complaint. To the extent that a response is required, Horizon denies each and every allegation in Paragraph 234 of the Complaint.

235. Per the Court's January 10, 2025 Memorandum Opinion and Order (ECF No. 25), the Court dismissed Claim 3 of the Complaint (ECF No. 3). Accordingly, no response is required to Paragraph 235 of the Complaint. To the extent that a response is required, Horizon denies each and every allegation in Paragraph 235 of the Complaint.

236. Per the Court's January 10, 2025 Memorandum Opinion and Order (ECF No. 25), the Court dismissed Claim 3 of the Complaint (ECF No. 3). Accordingly, no response is required to Paragraph 236 of the Complaint. To the extent that a response is required, Horizon denies each and every allegation in Paragraph 236 of the Complaint.

237. Per the Court's January 10, 2025 Memorandum Opinion and Order (ECF No. 25), the Court dismissed Claim 3 of the Complaint (ECF No. 3). Accordingly, no response is required to Paragraph 237 of the Complaint. To the extent that a response is required, Horizon denies each and every allegation in Paragraph 237 of the Complaint.

238. Per the Court's January 10, 2025 Memorandum Opinion and Order (ECF No. 25), the Court dismissed Claim 3 of the Complaint (ECF No. 3). Accordingly, no response is required to Paragraph 238 of the Complaint. To the extent that a response is required, Horizon denies each and every allegation in Paragraph 238 of the Complaint.

239. Per the Court's January 10, 2025 Memorandum Opinion and Order (ECF No. 25), the Court dismissed Claim 3 of the Complaint (ECF No. 3). Accordingly, no response is required to Paragraph 239 of the Complaint. and therefore, Horizon does not need to answer these

allegations. To the extent that a response is required, Horizon denies each and every allegation in Paragraph 239 of the Complaint.

240. Per the Court's January 10, 2025 Memorandum Opinion and Order (ECF No. 25), the Court dismissed Claim 3 of the Complaint (ECF No. 3). Accordingly, no response is required to Paragraph 240 of the Complaint. To the extent that a response is required, Horizon denies each and every allegation in Paragraph 240 of the Complaint.

241. Per the Court's January 10, 2025 Memorandum Opinion and Order (ECF No. 25), the Court dismissed Claim 3 of the Complaint (ECF No. 3). Accordingly, no response is required to Paragraph 241 of the Complaint. To the extent that a response is required, Horizon denies each and every allegation in Paragraph 241 of the Complaint.

242. Per the Court's January 10, 2025 Memorandum Opinion and Order (ECF No. 25), the Court dismissed Claim 3 of the Complaint (ECF No. 3). Accordingly, no response is required to Paragraph 242 of the Complaint. To the extent that a response is required, Horizon denies each and every allegation in Paragraph 242 of the Complaint.

243. Per the Court's January 10, 2025 Memorandum Opinion and Order (ECF No. 25), the Court dismissed Claim 3 of the Complaint (ECF No. 3). Accordingly, no response is required to Paragraph 243 of the Complaint. To the extent that a response is required, Horizon denies each and every allegation in Paragraph 243 of the Complaint. Answering further, to the extent a response is required and to the extent that Paragraph 243 refers to extrinsic documents not attached to or part of this Complaint, Horizon states that such documents speak for themselves. Horizon denies Paragraph 243 of the Complaint to the extent it misstates or mischaracterizes such documents.

244. Per the Court's January 10, 2025 Memorandum Opinion and Order (ECF No. 25), the Court dismissed Claim 3 of the Complaint (ECF No. 3). Accordingly, no response is required to Paragraph 244 of the Complaint. To the extent that a response is required, Horizon denies each and every allegation in Paragraph 244 of the Complaint.

245. Per the Court's January 10, 2025 Memorandum Opinion and Order (ECF No. 25), the Court dismissed Claim 3 of the Complaint (ECF No. 3). Accordingly, no response is required to Paragraph 245 of the Complaint. To the extent that a response is required, Horizon denies each and every allegation in Paragraph 245 of the Complaint.

246. Per the Court's January 10, 2025 Memorandum Opinion and Order (ECF No. 25), the Court dismissed Claim 3 of the Complaint (ECF No. 3). Accordingly, no response is required to Paragraph 246 of the Complaint. To the extent that a response is required, Horizon denies each and every allegation in Paragraph 246 of the Complaint.

247. Per the Court's January 10, 2025 Memorandum Opinion and Order (ECF No. 25), the Court dismissed Claim 3 of the Complaint (ECF No. 3). Accordingly, no response is required to Paragraph 247 of the Complaint. To the extent that a response is required, Horizon denies each and every allegation in Paragraph 247 of the Complaint.

248. In response to Paragraph 248 of the Complaint, Horizon incorporates by references its responses to the allegations contained in Paragraphs 1-247 of the Complaint as if set forth at length.

249. Per the Court's January 10, 2025 Memorandum Opinion and Order (ECF No. 25), the Court dismissed Claim 4 of the Complaint (ECF No. 3). Accordingly, no response is required to Paragraph 249 of the Complaint. To the extent that a response is required, Horizon denies each and every allegation in Paragraph 249 of the Complaint.

250. Per the Court's January 10, 2025 Memorandum Opinion and Order (ECF No. 25), the Court dismissed Claim 4 of the Complaint (ECF No. 3). Accordingly, no response is required to Paragraph 250 of the Complaint. To the extent that a response is required, Horizon denies each and every allegation in Paragraph 250 of the Complaint.

251. Per the Court's January 10, 2025 Memorandum Opinion and Order (ECF No. 25), the Court dismissed Claim 4 of the Complaint (ECF No. 3). Accordingly, no response is required to Paragraph 251 of the Complaint. To the extent that a response is required, Horizon denies each and every allegation in Paragraph 251 of the Complaint, including each of its subparts.

252. Per the Court's January 10, 2025 Memorandum Opinion and Order (ECF No. 25), the Court dismissed Claim 4 of the Complaint (ECF No. 3). Accordingly, no response is required to Paragraph 252 of the Complaint. To the extent that a response is required, Horizon denies each and every allegation in Paragraph 252 of the Complaint.

253. Per the Court's January 10, 2025 Memorandum Opinion and Order (ECF No. 25), the Court dismissed Claim 4 of the Complaint (ECF No. 3). Accordingly, no response is required to Paragraph 253 of the Complaint. To the extent that a response is required, Horizon denies each and every allegation in Paragraph 253 of the Complaint.

254. Per the Court's January 10, 2025 Memorandum Opinion and Order (ECF No. 25), the Court dismissed Claim 4 of the Complaint (ECF No. 3). Accordingly, no response is required to Paragraph 254 of the Complaint. To the extent that a response is required, Horizon denies each and every allegation in Paragraph 254 of the Complaint.

255. Per the Court's January 10, 2025 Memorandum Opinion and Order (ECF No. 25), the Court dismissed Claim 4 of the Complaint (ECF No. 3). Accordingly, no response is required

to Paragraph 255 of the Complaint. To the extent that a response is required, Horizon denies each and every allegation in Paragraph 255 of the Complaint.

256. Per the Court's January 10, 2025 Memorandum Opinion and Order (ECF No. 25), the Court dismissed Claim 4 of the Complaint (ECF No. 3). Accordingly, no response is required to Paragraph 256 of the Complaint. To the extent that a response is required, Horizon denies each and every allegation in Paragraph 256 of the Complaint.

257. Per the Court's January 10, 2025 Memorandum Opinion and Order (ECF No. 25), the Court dismissed Claim 4 of the Complaint (ECF No. 3). Accordingly, no response is required to Paragraph 257 of the Complaint. To the extent that a response is required, Horizon denies each and every allegation in Paragraph 257 of the Complaint.

258. In response to Paragraph 258 of the Complaint, Horizon incorporates by references its responses to the allegations contained in Paragraphs 1-257 of the Complaint as if set forth at length.

259. Horizon denies each and every allegation in Paragraph 259 of the Complaint. Answering further, to the extent that Paragraph 259 of the Complaint refers to allegations regarding the efficacy of Tepezza[®], the Court dismissed such allegations in its January 10, 2025 Memorandum Opinion and Order (ECF No. 25). Accordingly, no response is required to those allegations.

260. Horizon denies each and every allegation in Paragraph 260 of the Complaint. Answering further, to the extent that Paragraph 260 of the Complaint refers to allegations regarding the efficacy of Tepezza[®], the Court dismissed such allegations in its January 10, 2025 Memorandum Opinion and Order (ECF No. 25). Accordingly, no response is required to those allegations.

261. Horizon denies each and every allegation in Paragraph 261 of the Complaint.

262. Horizon denies each and every allegation in Paragraph 262 of the Complaint.

263. Horizon denies each and every allegation in Paragraph 263 of the Complaint.

Answering further, to the extent the allegations in Paragraph 263 refer to extrinsic documents not attached to or part of this Complaint, Horizon states that such documents speak for themselves. Horizon denies the allegations in Paragraph 263 of the Complaint to the extent they misstate or mischaracterize such documents.

264. Horizon denies each and every allegation in Paragraph 264 of the Complaint.

265. Horizon admits that in 2023, it hired Dr. Wenzhong Liu as an Executive Medical Director in 2023. Horizon denies each and every remaining allegation in Paragraph 265 of the Complaint.

266. Horizon denies each and every allegation in Paragraph 266 of the Complaint.

267. Horizon denies each and every allegation in Paragraph 267 of the Complaint.

Horizon further denies that Tepezza[®]'s FDA approved labeling is or ever was inadequate.

268. Horizon denies each and every allegation in Paragraph 268 of the Complaint, including each of its subparts.

269. Horizon denies each and every allegation in Paragraph 269 of the Complaint.

270. Horizon denies each and every allegation in Paragraph 270 of the Complaint.

271. Horizon denies each and every allegation in Paragraph 271 of the Complaint.

272. Horizon denies each and every allegation in Paragraph 272 of the Complaint.

273. Horizon denies each and every allegation in Paragraph 273 of the Complaint.

Answering further, to the extent that Paragraph 273 of the Complaint refers to allegations regarding the efficacy of Tepezza[®], the Court dismissed such allegations in its January 10, 2025

Memorandum Opinion and Order (ECF No. 25). Accordingly, no response is required to those allegations.

274. Horizon denies each and every allegation in Paragraph 274 of the Complaint. Answering further, to the extent that Paragraph 274 of the Complaint refers to allegations regarding the efficacy of Tepezza[®] or “overstat[ing] the benefits” of Tepezza[®] the Court dismissed such allegations in its January 10, 2025 Memorandum Opinion and Order (ECF No. 25). Accordingly, no response is required to those allegations.

275. Horizon denies each and every allegation in Paragraph 275 of the Complaint.

276. Horizon denies each and every allegation in Paragraph 276 of the Complaint.

277. In response to Paragraph 277 of the Complaint, Horizon incorporates by references its responses to the allegations contained in Paragraphs 1-276 of the Complaint as if set forth at length.

278. Horizon denies each and every allegation in Paragraph 278 of the Complaint.

279. Horizon denies each and every allegation in Paragraph 279 of the Complaint.

280. Horizon denies each and every allegation in Paragraph 280 of the Complaint.

281. Horizon denies each and every allegation in Paragraph 281 of the Complaint.

282. Horizon denies each and every allegation in Paragraph 282 of the Complaint.

283. Horizon denies each and every allegation in Paragraph 283 of the Complaint.

284. Horizon denies each and every allegation in Paragraph 284 of the Complaint.

285. Horizon denies each and every allegation in Paragraph 285 of the Complaint.

286. Horizon denies each and every allegation in Paragraph 286 of the Complaint.

287. Horizon denies each and every allegation in Paragraph 287 of the Complaint.

288. Horizon denies each and every allegation in Paragraph 288 of the Complaint.

289. Horizon denies each and every allegation in Paragraph 289 of the Complaint.

290. Horizon denies each and every allegation in Paragraph 290 of the Complaint.

291. Horizon denies each and every allegation in Paragraph 291 of the Complaint.

292. Horizon denies each and every allegation in Paragraph 292 of the Complaint.

In response to the Prayer for Relief paragraph following Paragraph 292, Horizon demands that judgment be entered in its favor and against plaintiff; that plaintiff's Complaint be dismissed, with prejudice; and that Horizon be awarded costs of suit and reasonable attorney's fees as allowed by law and such further and additional relief as this Court may deem just and proper.

Every allegation in the Complaint that is not specifically and expressly admitted in this Answer is hereby specifically and expressly denied, including any allegations contained in the headings of Plaintiff's complaint and the prayer for relief.

AFFIRMATIVE DEFENSES

1. The Complaint, in whole or part, fails to state a claim or cause of action against Horizon upon which relief can be granted.

2. Plaintiff's claims are barred by her failure to join necessary or indispensable parties.

3. Plaintiff's claims are subject to dismissal or transfer for failure to file or proceed in an appropriate court, venue, or division.

4. The doctrines contained in Restatement (Second) of Torts § 402A, Comment K, bar plaintiff's claims against Horizon in whole or in part.

5. The doctrine(s) contained in Restatement (Third) of Torts, Product Liability §§ 4 and 6, bar plaintiff's claims against Horizon in whole or in part.

6. Plaintiff's claims are barred, in whole or in part, because the labels and information accompanying the product at issue were approved by FDA or other appropriate regulatory agencies.

7. Plaintiff's claims are preempted, in whole or in part, by applicable federal law relating to the design, testing, producing, manufacturing, labeling, distributing, modeling, processing, and supply of Tepezza[®].

8. Plaintiff's claims are preempted in whole or in part, because plaintiff has not pled and cannot prove the existence of newly acquired information that would permit Horizon to change the label under the "changes being effected" regulation. *See* 21 C.F.R. § 317.70(c)(6).

9. Plaintiff's claims are preempted in whole or in part, because plaintiff seeks changes to the label that cannot be done without prior approval by FDA.

10. Plaintiff's claims are preempted in whole or in part, because FDA would not have approved the label changes sought by plaintiff.

11. Plaintiff's claims are barred, in whole or in part, by the deference that common law gives to discretionary actions by FDA under the Food, Drug, & Cosmetic Act.

12. Applicable statutes of limitations or repose bar plaintiff's claims in whole or in part.

13. The equitable doctrine of laches, waiver and/or estoppel bar plaintiff's claims in whole or in part.

14. Plaintiff's claims are barred, in whole or in part, because the plaintiff assumed the risks disclosed by the product labeling, by the prescribing physicians, or by other persons or entities.

15. Any alleged negligent or culpable conduct of Horizon, none being admitted, was so insubstantial as to be insufficient to be a proximate or substantial contributing cause of plaintiff's alleged injuries.

16. To the extent plaintiff used the product for "off-label" purposes, plaintiff's claims are barred.

17. The "learned intermediary" doctrine bars plaintiff's claims.

18. Plaintiff's claims are barred, in whole or in part, because the product at issue was designed, manufactured, marketed and labeled with proper warnings, information, cautions and instructions, in accordance with the state of the art and the state of scientific and technological knowledge.

19. Plaintiff's claims are barred, in whole or in part, because the labels and information accompanying the products at issue were approved by the U.S. Food and Drug Administration or other appropriate regulatory agencies.

20. Plaintiff's claims are barred, in whole or in part, by applicable products liability statutes or other law providing absolute or limited immunity or a disputable presumption of immunity against liability for pharmaceutical products approved by the FDA.

21. Plaintiff's claims are barred, in whole or in part, because the products at issue were not defective or unreasonably dangerous in that they complied with, at all relevant times, all applicable government safety standards.

22. Plaintiff's claims are barred, in whole or in part, because Horizon acted in good faith at all relevant times and gave adequate warning of all known or reasonably knowable risks associated with the use of Tepezza®.

23. Plaintiff's claims are barred, in whole or in part, because plaintiff's injuries, if any, were the result of conduct of plaintiff, independent third parties, and/or events that were extraordinary under the circumstances, not foreseeable in the normal course of events, and/or independent, intervening and superseding causes of the alleged injuries, including but not limited to plaintiff's pre-existing medical conditions.

24. If plaintiff suffered injury or damages as alleged, which is denied, such injury or damage resulted from acts or omissions of persons or entities for which Horizon is neither liable nor responsible or resulted from diseases and/or causes that are not related to or connected with any product sold, distributed, or manufactured by Horizon. Such acts or omissions on the part of others or diseases or causes constitute an independent, intervening and sole proximate cause of plaintiff's alleged injury or damages.

25. Plaintiff's claims are barred, in whole or in part, because plaintiff's alleged injuries, if caused by Tepezza[®], which is denied, were the result of plaintiff's own idiosyncratic reactions.

26. Plaintiff failed to mitigate, which limits plaintiff's damages, if any, in whole or in part.

27. Tepezza[®] was fit and proper for its intended purposes and the social utility of the drugs outweighed any possible risk inherent in the use of the products.

28. Horizon has no legal relationship or privity with plaintiff and owes no duty to plaintiff by which liability could be attributed to it.

29. The claims of plaintiff should be diminished in whole or in part in the amount paid to plaintiff by any party or non-party with whom plaintiff has settled or may settle.

30. Plaintiff's claims are barred, reduced and/or limited pursuant to applicable statutory and common law regarding limitations of awards, caps on recovery, and setoffs.

31. Notwithstanding the claims and contentions of plaintiff, plaintiff received all or substantially all of the benefit from the products that plaintiff hoped and intended to receive, and, to that extent, any damages and/or restitution that plaintiff might be entitled to recover from Horizon must be correspondingly reduced.

32. Plaintiff's causes of action are barred in whole or in part by plaintiff's own contributory/comparative negligence.

33. To the extent that the plaintiff is entitled to recover damages for medical expenses incurred prior to the conclusion of trial, such recovery is limited to the amounts paid and accepted as payment in full by any insurance benefit.

34. Plaintiff is barred from recovering any amounts that have been and/or will be covered by insurance required by and/or available pursuant to the Patient Protection and Affordable Care Act, 42 U.S.C. § 18001 et seq. (2010) ("ACA").

35. Any damages to which the plaintiff otherwise would be entitled shall be reduced by any amount which the plaintiff has received or with reasonable certainty will receive in the future from insurance required by the ACA. This answering defendant is entitled to an offset and/or credit for any portion of the plaintiff's medical expenses payable and/or within the coverage of insurance required by the ACA.

36. Plaintiff's recovery, if any, shall be reduced by those payments that plaintiff receives from collateral sources.

37. If plaintiff has been injured or damaged, no injury or damages being admitted, such injuries were not caused by a Horizon product.

38. Plaintiff's claims for punitive and/or exemplary damages are barred because such an award would violate Horizon's due process, equal protection and/or other rights under the

United States Constitution, the California Constitution, the Illinois Constitution, and/or other applicable state constitutions.

39. Plaintiff's claims for punitive and/or exemplary damages are barred because plaintiff has failed to allege conduct warranting imposition of punitive damages under Illinois law, California law, and/or other applicable state laws.

40. Plaintiff's claims for punitive and/or exemplary damages are preempted and/or barred, in whole or in part, by applicable federal law and/or state law.

41. Punitive and exemplary damages against Horizon cannot be recovered based on alleged fraudulent representation to the FDA. *See, e.g., Buckman Co. v. Plaintiffs' Legal Comm.*, 531 U.S. 341, 343 (2001).

42. Plaintiff's claims for punitive and/or exemplary damages are barred in whole or in part because plaintiff is not entitled to punitive and/or exemplary damages, no fault or other admissions being made.

43. Horizon did not intentionally harm plaintiff, nor did Horizon act with a deliberate and flagrant disregard for the safety of others. In fact, Horizon exercised reasonable care at all times alleged in the Complaint, and plaintiff has failed to establish by a preponderance of the evidence any entitlement to punitive and/or exemplary damages based on their allegations.

44. Horizon's conduct and/or acts were not willful, wanton, malicious, reckless, fraudulent or done with a conscious disregard for the rights of plaintiff, and/or the safety of the public. Nor do any of Horizon's conduct and/or acts demonstrate that Horizon acted with a high degree of moral culpability. In fact, Horizon exercised reasonable care at all times alleged in the Complaint, and plaintiff has failed to clearly establish any entitlement to exemplary and/or aggravated damages based on their allegations.

45. Plaintiff's claims are barred to the extent that plaintiff seeks relief under laws of states that do not govern plaintiff's claims.

46. Plaintiff's claims are barred because plaintiff's own negligence proximately caused and contributed to the injuries complained of and, therefore, the damages which might be recovered by plaintiff in this action, if any, should be reduced in proportion to the plaintiff's own negligence.

47. To the extent that California law applies, plaintiff's strict liability claims are barred in whole or in part. *See, e.g., Brown v. Superior Court*, 44 Cal. 3d 1049, 1072 (1988).

48. Horizon denies any and all culpability and liability, but if Horizon is ultimately found to be liable, then the liability of Horizon, if any, to plaintiff for non-economic loss is limited to its equitable share, determined in accordance with the relative culpability of all persons or entities contributory to the total liability for non-economic loss, including named parties and others over whom plaintiff could have obtained personal jurisdiction with due diligence.

49. Horizon hereby gives notice that it intends to rely upon such other defenses as may become available or apparent during the course of discovery and thus reserves its right to amend this Answer to assert such defenses.

JURY DEMAND

Defendant Horizon Therapeutics USA, Inc. demands a jury trial as to all issues so triable.

Dated: February 21, 2025

Respectfully Submitted,

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